



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Ray Threaded Fusion CageTM
Docket No. 97E-0087

APR 23 1999

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension application for U.S. Patent No. 4,961,740 filed by United States Surgical Corporation under 35 U.S.C. § 156. The patent claims the medical device Ray Threaded Fusion CageTM, premarket approval application PMA P950019.

In the October 13, 1998, issue of the Federal Register (63 Fed. Reg. 54719), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before April 12, 1999, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Neil D. Gershon, Esq.
United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06850

97E-0087

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Memorandum

APR 23 1999

Date:

From: **Brian J. Malkin, Associate Director for Patents and Hearings**
Health Assessment Policy Staff (HFY-20)

Subject: **Patent Term Restoration Application**
for Ray Threaded Fusion CageTM

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **97E-0087** stating that this particular patent is eligible for regulatory review. The Patent Number is **4,961,740**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.